

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	) ) MDL NO. 1456 ) Civil Action No. 01-12257-PBS ) Subcategory Case No: 03-10643-PBS
THIS DOCUMENT RELATES TO:  <i>The City of New York, et al.</i>  v.  <i>Abbott Laboratories, et al.</i>	) ) Judge Patti B. Saris ) ) ) ) ) )

**PLAINTIFFS' LOCAL RULE 56.1 STATEMENT OF  
UNDISPUTED MATERIAL FACTS AS TO DEY L.P. AND DEY, INC.**

Pursuant to Rule 56.1 of the Local Rules of this Court, plaintiffs hereby submit their Statement of Undisputed Material Facts Applicable to Defendants Dey L.P., and Dey, Inc. (collectively "Dey") in support of their Motion for Partial Summary Judgment.

**I. DEY SPECIFIC FACTS**

1. The Dey drugs and NDCs that have been examined in connection with this motion are set forth in Exhibit A hereto. This exhibit also sets forth Dey's Published AWP's and WACs for these drugs and NDCs. The exhibit notes which NDCs are associated with package sizes that set the FUL.

2. The specific Dey drugs at issue are the Albuterol .83 mg/ml solution and the Albuterol 90 MCG Inhaler.

3. Dey has entered into and executed the federal Medicaid rebate agreement pursuant to 42 U.S.C. § 1396r-8. *See*, Deposition of Dey, L.P. and Dey, Inc. 30(b)(6) (Pamela Marrs) 5/15/08 (Exhibit B) at 38:6-10 (hereinafter "Dey 30(b)(6) (Marrs) 5/15/08 Dep. (Exhibit

B’’). Defendants Dey, L.P. and Dey, Inc.’s Answer and Affirmative Defenses to Plaintiffs’ Revised First Amended Consolidated Complaint (“Dey Answer”)[Dkt #4853] at ¶132.

4. Dey understands that pharmacies that dispense Dey drugs to Medicaid beneficiaries get reimbursed by state Medicaid agencies, including New York’s. *See* Dey 30(b)(6) (Marrs) 5/15/08 Dep. (Exhibit B) at 37:2-6.

5. Dey understands that state Medicaid reimbursements are based on AWP. *See* Dey 30(b)(6) (Marrs) 5/15/08 Dep. (Exhibit B) at 149:3-9.

6. Debbie Collie testified that her handwritten notes of a managers’ meeting in 1995 reflected a decision to use the district sales managers to deal directly with state Medicaid offices to determine reimbursement landscape for Dey’s pricing and marketing activities. Deposition of Deborah Jane Collie dated 2/19/03 (“Collie 2/19/03 Dep.”)(Exhibit C) at 134:9-135:14; Collie 2/19/03 Dep. Exhibit 741, Bates DL-TX-0097756 (Exhibit C).

7. Carrie Jackson testified that she was instructed to gather information about the Medicaid reimbursement rates in all 50 states, and regularly update that information for use by Dey sales and marketing personnel, and that she did so. *See* Deposition of Carrie Jean Jackson dated 4/18/03 (“Jackson 4/18/03 Dep.”)(Exhibit D) at 22:16-23:10; Jackson Dep. Exhibit 230 (Exhibit D).

8. Dey’s handbook of sales protocols sets out procedures for selling to different classes of trade, and lists State Medicaid Offices as a type of sales call. *See* Dey Sales Call Protocol, Bates DL-TX-0091427(Exhibit E). Addressing these calls, the handbook says, “Sales calls to state Medicaid offices are important to keep abreast of the rapidly changing Medicaid landscape. The most important issues are determining if Dey products are reimbursed by the

state and at what rate. Be sure to be up-to-date as to procedures for approval of new product entries.” *Id.*

9. Dey’s sales call protocol handbook goes on to direct District Sales Managers to “meet with program director or equivalent,” “[d]etermine if Dey products are ‘covered’ by [the] state,” “[i]f so, verify reimbursement rates,” and “[d]iscuss methods used to determine reimbursement rates, a. AWP + dispensing fee[,] b. AWP – x% + dispensing fee[,] MAC + dispensing fee[, and] d. [a]ny other method.” *Id.*

10. Dey also admits that its own documents reveal that certain sales and marketing people were aware that Medicaid reimbursements were made on the basis of Dey’s published prices. *See* Dey 30(b)(6) (Marrs) 5/15/08 Dep. (Exhibit B) at 187:14-188:8.

11. Dey knew that eligibility for reimbursement by Medicaid was important to its customers. *See* Deposition of Dey, L.P. and Dey, Inc. 30(b)(6) (Pamela Marrs) dated 7/10/08 (“Dey 30(b)(6) (Marrs) 7/10/08 Dep.”) (Exhibit F) at 450:5-15.

12. Dey’s sales protocol handbook directs sales personnel to “[d]iscuss the Medicaid reimbursement rate,” and “[i]nform R.Ph. if our products are covered,” in the context of describing the procedure for calling on an independent retail pharmacy owner or manager. Dey Sales Call Protocol, Bates DL-TX-0091417 (Exhibit E)

### **Dey Set and Reported Its AWP and WACs**

13. At all times, from 1997 to 2005, Dey reported both AWP and WAC for its drugs to all three of the national compendia – First DataBank, RedBook and Medi-Span. *See* Dey 30(b)(6) (Marrs) 5/15/08 Dep. (Exhibit B) at 75:17-21; 74:13-76:21; 136:12-18.

14. Dey knew and controlled the AWP and WACs for its drugs that were published by the national drug pricing compendia. *See* Dey 30(b)(6) (Marrs) 5/15/08 Dep. (Exhibit B) at

133:16-136:10; Deposition of Robert Mozak dated 11/6/02 (“Mozak 11/6/02 Dep.”) (Exhibit G) at 509:01-513:20.

**15.** First Databank, Redbook and Medispan sent requests to Dey to verify the accuracy of the AWP and WACs for its drugs and Dey confirmed and acknowledged that the published prices were the same as those Dey had submitted for publication. *See* Dey 30(b)(6) (Marrs) 5/15/08 Dep. (Exhibit B) at 133:16-136:2.

**16.** Dey knew of the Federal Upper Limit (FUL) and that it is a limitation on reimbursement below AWP that is set on published prices. *See* Dey 30(b)(6) (Marrs) 5/15/08 Dep. (Exhibit B) at 145:11-18.

**Dey’s Published AWP and WACs had No Relationship to Actual Prices**

**17.** Dey admits that its reported AWP are not tethered to the actual prices anyone pays. AWP has no connection whatsoever to actual prices Dey charges to any customers. *See* Dey 30(b)(6) (Marrs) 5/15/08 Dep. (Exhibit B) at 131:8-133:15 (practice of setting AWP at launch and never changing it to reflect falling prices); 138:6-21; Deposition of Robert Mozak dated 11/1/01 (“Mozak 11/1/01 Dep.”) (Exhibit H) at 120:23-121:6; Mozak 11/6/02 Dep. (Exhibit G) at 685:02-688:20; Mozak 11/6/02 Dep. Exhibit 345 (Exhibit G) (reporting the increase of a product’s AWP while the actual price of the product remained unchanged); Deposition of Robert Mozak dated 3/13/03 (“Mozak 3/13/03 Dep.”) (Exhibit I) at 930:13-21 (AWP is known not to be a real price); 1026:6-8; Deposition of Dey, L.P. and Dey, Inc. 30(b)(6) (Gary Walker) dated 7/9/08 (“Dey 30(b)(6)(Walker 7/9/08 Dep.”) (Exhibit J) at 482:05-438:10.

**18.** Wholesalers have contracts with Dey. *See* Dey 30(b)(6) (Marrs) 5/15/08 Dep. (Exhibit B) at 274:20-285:16; Deposition of Dey, L.P. and Dey, Inc. 30(b)(6) (Gary Walker)

dated 5/14/08 (“Dey 30(b)(6)(Walker) 5/14/08 Dep.”) (Exhibit M) at 263:01-264:17; Dey 30(b)(6)(Walker) 5/14/08 Dep. Exhibit 15 (Exhibit M).

**19.** Some of Dey’s wholesaler contracts provide for product specific pricing and incentives. Product specific incentives reduce wholesaler's acquisition cost for the relevant Dey product. *See* Dey 30(b)(6)(Marrs) 7/10/08 Dep. (Exhibit K) at 541:8-542:9; 543:22-544:14; Deposition of Charles Rice dated 10/30/01 (“Rice 10/30/01 Dep.”) (Exhibit L) at 87:23-93:13. Some wholesaler contracts provide for baseline (across the board rebates). *See* Dey 30(b)(6)(Marrs) 5/15/08 Dep. (Exhibit B) at 91:10-93:1; 274:20-279:8; Dey 30(b)(6) (Walker) 5/14/08 Dep. (Exhibit M) at 268:5-20. Baseline rebates reduce wholesaler's acquisition cost for all Dey products. *See* Dey 30(b)(6) (Marrs) 7/10/08 Dep. (Exhibit K) at 541:8-542:9; 543:22-544:14; Rice 10/30/01 Dep. (Exhibit L) at 94:25-97:2.

**20.** Of all Dey’s sales to wholesalers, half are subject to chargebacks. *See* Dey 30(b)(6) (Walker) 7/9/08 Dep. (Exhibit J) at 518:14-519:6.

**21.** Dey negotiates contract prices to the majority of its non-wholesaler customers, principally pharmacies, which are below the WAC for each of its drugs. *See* Dey 30(b)(6) (Walker) 7/9/08 Dep. (Exhibit J) at 408:7-409:5; Dey 30(b)(6) (Marrs) 5/15/08 Dep. (Exhibit B) at 82:13-16; Rice 10/30/01 Dep. (Exhibit L) at 199:19-205:2; Rice 10/30/01 Dep. Exhibit 78 (Exhibit L).

**22.** Dey pays its non-wholesaler customers rebates, discounts, floor stock adjustments, fees, incentives and other pricing allowances that further reduce their actual acquisition cost. *See* Dey 30(b)(6) (Marrs) 5/15/08 Dep. (Exhibit B) at 107:6-111:18; Deposition of Robert Mozak dated 4/30/02 (“Mozak 4/30/02 Dep.”) (Exhibit N) at 443:14-445:16; 447:11.

23. The majority of Dey's sales are made to various contract customers who buy at prices below WAC, and only "some" purchase DEY products from wholesalers without the benefit of a contract. Deposition of Russell Johnston dated 12/11/08 (Johnston 12/11/08 Dep.") (Exhibit O) at 456:5-457:7.

24. Dey knew of the OIG Guidelines. See Deposition of Dey, L.P. and Dey, Inc. 30(b)(6) (Pamela Marrs) dated 10/2/08 ("Dey 30(b)(6)(Marrs) 10/02/08 Dep.") (Exhibit P) at 658:14-660:1.

25. At all times, from 1997 to 2005, Dey has calculated on a quarterly basis the average manufacturer's price ("AMP") for all its products and reported it as required by the federal rebate statute. See Dey 30(b)(6) (Marrs) 5/15/08 Dep. (Exhibit B) at 168:10-169.

Dated: May 15, 2009

Respectfully submitted,

**KIRBY McINERNEY, LLP**  
825 Third Avenue  
New York, New York 10022  
(212) 371-6600

By: /s/ Joanne M. Cicala  
Joanne M. Cicala  
James P. Carroll Jr.  
Jocelyn Normand  
Kathryn Bale Allen

*Counsel for the City of New York and New York  
Counties in MDL 1456 except Nassau and Orange*

Ross B. Brooks, Esq.  
**MILBERG LLP**  
One Pennsylvania Plaza  
New York, NY 10119  
(212) 594-5300

*Special Counsel for the County of Nassau*

Theresa A. Vitello, Esq.  
**LEVY PHILLIPS &  
KONIGSBERG, LLP**  
800 Third Ave.

New York, NY 10022  
(212) 605-6205

*Counsel for the County of Orange*

**CERTIFICATE OF SERVICE**

I, James P. Carroll Jr., hereby certify that I caused a true and correct copy of the foregoing PLAINTIFFS' LOCAL RULE 56.1 STATEMENT OF UNDISPUTED MATERIAL FACTS AS TO DEY L.P. AND DEY, INC., to be served on counsel of record via electronic service pursuant to paragraph 11 of Case Management Order No. 2, by sending a copy to LexisNexis File and Serve for posting and notification to all parties. The confidential exhibits to the foregoing have been served electronically directly to counsel for Dey L.P. and Dey, Inc.

Dated: May 15, 2009

\_\_\_\_\_/s/\_\_\_\_\_  
James P. Carroll, Jr.  
Kirby McInerney LLP  
825 Third Avenue, 16th Floor  
New York, NY 10022  
(212) 371-6600

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**CONFIDENTIAL EXHIBITS**

**TO  
PLAINTIFFS' LOCAL RULE 56.1 STATEMENT OF  
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**MAY 15, 2009**

**SUBJECT TO MOTION FOR LEAVE TO FILE UNDER SEAL**